(2) More thorough explanation of how the certified limits were determined.

(3) A narrower range between the upper and lower certified limits than that proposed.

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [*product name*], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 161.180 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that is determined to be toxicologically significant.

§ 161.190 Physical and chemical characteristics.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the physical and chemical characteristics data requirements and the substance to be tested.

Kind of data required	(b) Notes	All general use patterns (requirements are the same for every use pattern)	Test substance		Guidelines reference No.
			Data to support MP	Data to support EP	
Color		[R]	MP and TGAI	EP* and TGAI	63–2
Physical state		[R]	MP and TGAI	EP* and TGAI	63–3
Odor		[R]	MP and TGAI	EP* and TGAI	63–4
Melting point	(1)	[R]	TGAI	TGAI	63–5
Boiling point	(2)	[R]	TGAI	TGAI	63–6
Density, bulk density, or specific gravity		[R]	MP and TGAI	EP* and TGAI	63–7
Solubility		[R]	TGAI or PAI	TGAI or PAI	63–8
Vapor pressure		[R]	TGAI or PAI	TGAI or PAI	63–9
Dissociation constant		[R]	TGAI or PAI	TGAI or PAI	63–10
Octanol/water partition coefficient	(3)	[CR]	PAI	PAI	63–11
pH	(4)	[CR]	MP and TGAI	EP* and TGAI	63–12
Stability		[R]	TGAI	TGAI	63–13
Oxidizing or reducing action	(5)	[CR]			
Flammability	(6)	[CR]	MP	EP*	63–15
Explodability	(7)	[R]	MP	EP*	63–16
Storage stability		[R]	MP	EP*	63–17
Viscosity	(8)	[CR]	MP	EP*	63–18
Miscibility	(9)	[CR]	MP	EP*	63–19
Corrosion characteristics		[R]	MP	EP*	63–20
Dielectric breakdown voltage	(10)	[CR]		EP*	63–21
Other requirements: Submittal of samples	(11)	[CR]	MP, TGAI, PAI	EP*, TGAI, PAI	64–1

Key: R = Required; CR = Conditionally Required; [ ] = Brackets (*i.e.*, [R],[CR]) indicate data requirements that apply when an experimental use permit is being sought; MP = Manufacturing Use Product, EP* = End Use Product; asterisk indicates those registrants that end-use applicants (*i.e.*, formulators) need not satisfy, if their active ingredient(s) is (are) purchased from a registered source; TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.

(b) *Notes.* The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Required if technical chemical is a solid at room temperature.
(2) Required if technical chemical is a liquid at room temparature.
(3) Required if technical chemical is organic and non-polar.
(4) Required if test substance is dispersible with water.
(5) Required if product contains an oxidizing or reducing agent.
(6) Required if product contains combustible liquids.
(7) Required if product is potentially explosive.
(8) Required if product is a liquid.
(9) Required if product is a emulsifiable liquid and is to be diluted with petroleum solvents.
(10) Required if end-use product is a liquid and is to be used around electrical equipment.
(11) Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end use products produced by an integrated system must be submitted on a case-by-case basis.

[49 FR 42881, Oct. 24, 1984, as amended at 58 FR 34203, June 23, 1993]

Subpart D—Data Requirement Tables

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted. Redesignated and amended at 72 FR 60253–60255, Oct. 24, 2007.

§ 161.202 Purposes of the registration data requirements.

(a) *General.* The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) [Reserved]

(c) *Residue chemistry.* (1) Residue Chemistry Data are used by the Agency to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.

(2) Information on the chemical identity and composition of the pesticide product, the amounts, frequency and time of pesticide application, and results of test on the amount of residues remaining on or in the treated food or feed, are needed to support a finding as to the magnitude and identity of residues which result in food or animal feed as a consequence of a proposed pesticide usage.

(3) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance, and to support practicable methods for removing residues that exceed any proposed tolerance.

(d) *Environmental fate*—(1) *General.* The data generated by environmental fate studies are used to: assess the toxicity to man through exposure of humans to pesticide residues remaining after application, either upon reentering treated areas or from consuming inadvertently-contaminated food; assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides. Another specific purpose of the environmental fate data requirements is to help applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.

(2) *Degradation studies.* The data from hydrolysis and photolysis studies are used to determine the rate of pesticide degradation and to identify pesticides that may adversely affect nontarget organisms.

(3) *Metabolism studies.* Data generated from aerobic and anaerobic metabolism studies are used to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.

(4) *Mobility studies.* These data requirements pertain to leaching, adsorption/desorption, and volatility of pesticides. They provide information on the mode of transport and eventual destination of the pesticide in the environment. This information is used to assess potential environmental hazards related to: contamination of human and animal food; loss of usable land and water resources to man through contamination of water (including ground water); and habitat loss of wildlife resulting from pesticide residue movement or transport in the environment.

(5) *Dissipation studies.* The data generated from dissipation studies are used to assess potential environmental hazards (under actual field use conditions) related to: reentry into treated areas; hazards from residues in rotational crop and other food sources; and the loss of land as well as surface and ground water resources.

(6) *Accumulation studies.* Accumulation studies indicate pesticide residue levels in food supplies that originate from wild sources or from rotational crops. Rotational crop studies are necessary to establish realistic crop rotation restrictions and to determine if tolerances may be needed for residues